

Remarks

Upon entry of the foregoing amendments, claims 16 – 34 are under consideration. Applicants have amended claim 16 and added new claims 17 – 34 to more clearly define the present invention. New claims 37 – 56 are directed to polypeptides based on SEQ ID NO:2 in general. More particularly, new claims 17 – 34 are directed to structural elements within the polypeptides of the present invention. Specifically, new claims 17 – 30 are directed to domains within Zneu1, including two HSMHC3W5A domains, HSM1 (amino acid residues 20 to 104 of SEQ ID NO:2) and HSM2 (amino acid residues 178 to 273 of SEQ ID NO:2); and two EGF-like domains, EGF1 (amino acid residues 105 to 135 of SEQ ID NO:2), and EGF2 (amino acid residues 136 to 177 of SEQ ID NO:2). Basis for new claims 17 – 30 can be found in the Specification as originally filed, and specifically in original claims 7 – 9, and at pg. 11, lines 5-25, and pg. 23, line 5 through pg. 24, line 2. New claims 31 – 34 are directed to compositions comprising a pharmaceutically acceptable carrier and the polypeptides of the present invention. Basis for these new claims can be found in the Specification as originally filed, and specifically at pg. 31, line 5 through pg. 32, line 18.

The present amendments add no new matter.

THE §101 REJECTION

The Examiner has rejected claim 16 under 35 U.S.C. §101, alleging that the claimed invention is not supported by either a substantial asserted utility or a well established utility, as the claimed polypeptides are directed to “an orphan neuro-growth factor.” Specifically, the Examiner has alleged that the claimed polypeptides do not have substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use.

Applicants traverse. Applicants respectfully submit that the rejection is contrary to both the law and the United States Patent Office’s own examination guidelines. The application of these standards to biotechnology inventions is discussed in the January 5, 2001 Utility

Examination Guidelines, which state:

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An invention has a well-established utility if a person of ordinary skill would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties...), and the utility is specific, substantial, and credible...

See e.g. Utility Examination Guidelines, 66 F.R. 4 at pg. 1098, §II.B.1(c)(1). Moreover, “[a] patent examiner must accept a utility asserted by an applicant unless the Office has sound scientific reasoning to rebut the assertion.” *Id.*

As stated in the Specification, the Zneu1 polypeptides of the present invention would be useful “in angiogenesis” due to Zneu1’s association and structural similarities with the endothelial-specific gene Notch 4. Applicants also assert that one skilled in the art would immediately recognize that the polypeptides of the present invention have a well-known biological function based on Zneu1’s structural similarity to Notch 4. Thus, Applicants assert that the polypeptides of the present invention would be recognized by one skilled in the art as having a substantial asserted utility and a well-established utility. Consequently, Applicants request that the Examiner withdraw the present rejection under 35 U.S.C. §101.

THE §112, FIRST PARAGRAPH REJECTION

The Examiner has rejected claim 16 under 35 U.S.C. §112, first paragraph, alleging “one skilled in the art clearly would not know how to use the claimed invention.”

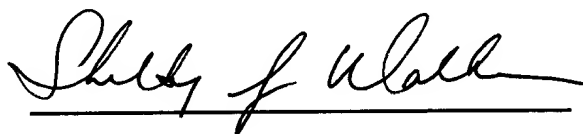
Applicants traverse. Applicants have indeed taught how to use the instant invention. As discussed above, Applicants have shown that the polypeptides of the present invention share numerous structural similarities with Notch 4. Consequently, Applicants have shown a biological activity for the polypeptides of the present invention. Thus, Applicants assert that the Specification more than adequately teaches how to use the present invention.

Dated: September 24, 2003

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the Application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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Enclosures:

Petition and Fee for Extension of Time (in duplicate)
Amendment Fee Transmittal (in duplicate)
Postcard

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